Metered Dose Inhalers: The Transition to Ozone-Safe Propellants

Metered dose inhalers (MDIs) propelled by ozone-depleting CFCs are being gradually and cautiously phased out. EPA urges all patients to consult with their doctors or health care providers to discuss the transition to a CFC-free MDI.

BACKGROUND

Chlorofluorocarbons (CFCs) deplete the stratospheric ozone layer. A thinner ozone layer allows more harmful ultraviolet (UV) radiation to reach the Earth's surface. Overexposure to UV radiation can lead to serious health effects, such as skin cancer, cataracts, and immune suppression as well as serious ecological impacts.

As a Party to the Montreal Protocol, the United States has committed to phasing out and eventually eliminating substances that deplete the ozone layer, including CFCs. EPA estimates that ***actions to protect and restore the ozone layer will save an estimated 6.3 million lives*** that would have otherwise been lost to skin cancer.

The shift to CFC-free MDIs is part of a larger transition that has affected many consumer and industrial products and sectors over the last several decades. In 1996, the United States prohibited the production and import of CFCs except for certain essential uses. In fact, MDIs used for the treatment of asthma and chronic obstructive pulmonary disease are among the ***last uses to switch to ozone-safe alternatives***.

Why do MDIs contain propellants?

MDIs rely on a propellant to push medication out of the inhaler. Two common propellants are CFCs and HFAs (hydrofluoroalkanes). HFAs are ozone-safe and have replaced ozone-depleting CFCs in many sectors. Neither CFCs nor HFAs are medications; they serve only as the propellant that pushes the medication out of the inhaler.

How were CFC albuterol MDIs removed from the market?

As CFC-free alternatives penetrate the market, EPA coordinates with the United States Food and Drug Administration (FDA) to determine when particular MDIs that rely on CFCs are no longer essential. All alternatives undergo rigorous research and testing to ensure safety and efficacy for patients. FDA's evaluation is based on criteria such as the availability and convenience of ozone-safe alternatives and the costs and benefits of the transition.

In 2005, FDA removed albuterol's essential use designation, which meant that albuterol MDIs containing CFCs could no longer be sold after 2008. This created a transition period of over three years. ***Only albuterol MDIs containing CFCs are phased out.*** Albuterol MDIs propelled by ozone-safe HFAs are available, including Proventil HFA, Ventolin HFA, Ivax's albuterol sulfate HFA, and Xopenex (HFA).

Why is my HFA MDI more expensive?

Your HFA MDI may be more expensive because generic forms are not currently available. To assist patients facing the higher costs, MDI manufacturers have instituted financial assistance programs. For low-income patients, manufacturers have eased the income restrictions to receive free and discounted medicines and have streamlined the procedures to apply for assistance. Coupons for free and discounted HFA albuterol MDIs are available through physicians, at pharmacies, and for download from individual manufacturer websites. More information is available at http://epa.gov/ozone/title6/exemptions/inhalers.html, which provides links to websites by FDA, manufacturers, and patient advocacy groups.